Operating Instructions
Monopolar RF Pens

Index: B **CE0124**

Applies to:	RF PEns No. 92043; 92044; 92047; 92048: 92 243; 92244;92245; 92247; 92248 Peak voltage 4,3 KVp
Description:	The pens are intended for connecting and control RF-electrodes. A RF cable connects the pen with the RF generator. Activation occurs with switches on RF handpiece.
Warning notes:	New pens must be cleaned and sterilised according to a validated procedure (DIN EN 554) using saturated steam for at least 10 minutes before use. Alkaline cleansers and solutions (ph>7) can damage the pens. Check the insulation for absence of pressure marks or damages prior to each use. Never use damaged pens. Do not operate in the presence of flammable substances. The respective label indicates the maximum output voltage.
Preparations for cleaning:	Disassembly is not required.
Manual cleaning:	Disinfect and clean pens with a soft brush or a a plastic fleece immediately after each use since otherwise particles or dried secretions can stick to them, making later cleaning and sterilisation difficult or even impossible. Make sure to clean and flush hidden areas several times.
Cleaning with an automatic machine:	The following cleaning machines were used during validation: - Hamo LS 76 cleaning automaton with neutral cleanser and rinse aid (neodisher mediclean and neodisher mediklar) - Cleanmaquet 203 with neutral cleanser (neodisher mediclean) - Miele 67736 C1 and Miele 67736 C2 with neutral cleanser (neodisher mediclean)
Sterilisation	Steam sterilisation in the autoclave: 134℃ in saturated steam for 10 minutes, drying in vacuum for 15 minutes. Heed DIN EN 554 (Sterilization of medical devices - Validation and routine control of sterilization by moist heat) when sterilising. The following autoclaves were used during validation: - Selectomat S3000; 134℃, 5 min, vacuum drying for 15 min - Varioclav 400E; 134℃, 5 min, vacuum drying for 15 mi n - Vaculab 969 S3000; 134℃, 5 min, vacuum drying for 1 5 min - KS666-2ED; 134℃, 5 min, vacuum drying for 15 min Temperature up to 95℃
Restrictions for reconditioning:	The product's service life depends on the degree of wear and damage. Frequent reconditioning has only little effect on the service life.
Function test:	Check the insulation for absence of pressure marks or damages prior to each use. Do not use damaged pens or pens with pressure marks.
Packaging, storing, transporting, handling	Store pens in a clean, dry environment. You should store them separately in a protective container with separate compartments or sealed in foil. Always transport, clean, maintain, sterilise and store pens with utmost care. This applies in particular to fine tips or other delicate areas. The operator must ensure the sterile state is maintained after sterilisation.